UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION	MDL No. 15-2666 (JNE/DTS) MEMORANDUM **(FILED UNDER SEAL)**

This Document Relates to All Cases

This multidistrict litigation ("MDL") is before the Court on Defendants' motions to exclude the expert testimony of Drs. William Jarvis, Jonathan Samet, Michael Stonnington, and Said Elghobashi, under Federal Rule of Evidence 702. For the reasons set forth below, the Court grants the motions and grants summary judgment for Defendants.

BACKGROUND

Plaintiffs allege that Defendants' Bair Hugger Forced Air Warming Device ("the Bair Hugger") caused their periprosthetic joint infection ("PJI") as a sequela to orthopedic-implant surgery. The Bair Hugger, a device for keeping surgical patients warm, consists of a portable heater or blower connected by a flexible hose to a disposable blanket that is placed over (or in some cases under) surgical patients. The Bair Hugger intakes air from the surrounding area and passes it through the intake filter and internal air pathways of the machine and into an outlet hose. The warm air travels through the distal end hose, which does not have an air filter, and into the blanket, providing warmth to the patient during surgery. Because the patient's torso (in hip and knee surgeries) and

the Bair Hugger blanket are covered with surgical draping, the warm air does not blow directly onto the surgical site.

Plaintiffs allege two theories about how the Bair Hugger can cause PJI. First, Plaintiffs allege that the Bair Hugger's warm air flow escapes the bottom edge of the surgical drape, creating turbulence in the operating room ("OR"), which lifts squames (shed skin flakes that can carry bacteria) into the air and into the surgical site, and increases the risk of infection. The Court has termed this theory the "airflow disruption" theory. Dr. Elghobashi, a recognized expert in computational fluid dynamics ("CFD"), built a CFD simulation to model this theory. The simulation purports to show that the Bair Hugger generates extreme turbulence in the OR causing squames to reach the surgical site. Second, Plaintiffs claim that the device, which lacks an adequate filtration system, emits contaminants into the OR, and thus, increases the bacterial load reaching the surgical site. The Court has labeled this second theory the "dirty machine" theory.

Plaintiffs' three medical experts—Drs. Jarvis, Samet, and Stonnington—have opined that the Bair Hugger causes PJI. For purposes of general causation, the issue in this litigation is whether use of the Bair Hugger device increases the risk of PJI compared to the risk of infection when the device is not used. The medical experts reviewed many studies that support both theories of causation, including Dr. Elghobashi's CFD simulation, and one epidemiological study that found a statistically significant association between the Bair Hugger and PJI. Defendants argue, however, that the scientific literature expressly disclaims causation and asks the Court to exclude these opinions for this reason.

In its December 13th, 2017 *Daubert* order, this Court found the testimony of Plaintiffs' engineering expert—Dr. Elghobashi—and Plaintiffs' medical experts—Drs. Jarvis, Samet, and Stonnington—to be admissible. The Court found that Dr. Elghobashi ran a simulation, using accepted physics principles, to show how the Bair Hugger's warm air flow could cause squames to float upward toward the surgical wound. The Court also found that Drs. Jarvis, Samet, and Stonnington relied on Dr. Elghobashi's testimony as well as the epidemiological study for reliable mechanistic and statistical evidence that the Bair Hugger causes PJI.

Defendants had also argued that if the Court excluded Plaintiffs' three general causation experts, then summary judgment would be appropriate. Because the Court denied Defendants' *Daubert* motion, the Court subsequently denied Defendants' summary judgment motion.

In April 2018, the Court heard argument on the parties' case-specific dispositive motions in *Gareis*, the first bellwether trial in the MDL.[1] The Court denied Defendants' motion to exclude expert testimony by Dr. Elghobashi. The Court also denied Defendants' motion to exclude expert testimony by Drs. Jarvis and Stonnington. *Id.*

[1] This was not the first scheduled bellwether trial. On May 30, 2017, pursuant to Pretrial Order No. 19, the Court selected eight bellwether cases from the parties' proposed cases and then each party exercised one strike to finalize the six cases in the "Final Bellwether Trial Pool." On June 16, 2017, the Court determined the order of these six bellwether trials, listing *Gareis* as last. Because the first five cases never made it to trial, *Gareis* became the first bellwether to go to trial. On March 13, 2018, the Court repopulated the bellwether pool and the parties selected an additional twelve potential bellwethers ("the Bellwethers Second") per Pretrial Order No. 24.

In May 2018, the Court heard pretrial motions in *Gareis*. The Court granted Defendants' motion to exclude evidence pertaining to Plaintiffs' "dirty machine" theory. The Court determined that "Plaintiffs have no evidence that however many *Staphylococcus epidermidis* might be in the Bair Hugger, that that number would have a meaningful impact on the bacterial load of that pathogen in the operating room." *Gareis* 16-cv-4187, ECF No. 306 (Order re Mot. in Lim.) at 2. Thus, the Court held that Plaintiffs failed to introduce sufficient proof to support this theory of causation. *Id.*

The trial commenced on May 14, 2018 and ended May 30, 2018. Drs. Elghobashi, Jarvis, and Stonnington all testified. On May 30th, a jury returned a verdict in favor of Defendants. The jury concluded that Plaintiffs did not prove by a preponderance of the evidence that the Bair Hugger caused the plaintiff's infection. The jury further concluded that Plaintiffs did not prove by a preponderance that the Bair Hugger system was unreasonably dangerous and a safer alternative design existed.

In August 2018, 3M requested leave to move for reconsideration of the Court's *Daubert* rulings. In their letter request, Defendants argued that new evidence undermines the scientific support proffered by Plaintiffs' medical experts in their general causation opinions. Under Local Rule 7.1(j), a party must show "compelling circumstances" to obtain permission from the court to move for reconsideration. Motions for reconsideration serve "the limited function of correcting manifest errors of law or fact or . . . present[ing] newly discovered evidence." *Bradley Timberland Res. v. Bradley Lumber Co.*, 712 F.3d 401, 407 (8th Cir. 2013). On November 20, 2018, the Court

concluded that Defendants demonstrated compelling circumstances and granted the request.[2]

On January 24, 2019, Defendants filed their motion to reconsider and asked the Court to exclude the testimony of Plaintiffs' medical experts and Dr. Elghobashi pursuant to Federal Rule of Evidence 702 and grant summary judgment in favor of Defendants. On February 21, 2019, Plaintiffs filed their Memorandum in Opposition. Defendants replied on March 14, 2019. On May 6, 2019, the Court posed three additional questions to clarify issues relating to both general and specific causation. The parties responded on May 16, 2019. Both parties also presented their arguments at a hearing on June 12, 2019.

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. It states that a qualified expert witness may testify to "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence or to determine a fact in issue" and if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

[2] Prior to granting Defendants' request to file a motion for reconsideration, the Court had directed the two joint nominees in the Bellwethers Second—*Hives* and *Axline*—to prepare for trial. *Axline* was set to be tried on December 3, 2018. But by November 15, 2018, *Hives* had been dismissed and Plaintiffs' counsel had indicated that they intended to dismiss the remaining claims in *Axline*. ECF No. 1597 (Pretrial Order No. 27).

The key inquiry is whether the experts' methodology is reliable enough to assist the trier of fact. To aid in this inquiry, the Supreme Court in *Daubert* identified four nonexclusive factors a court can apply: "(1) whether the theory or technique 'can be (and has been) tested'; (2) 'whether the theory or technique has been subjected to peer review and publication'; (3) 'the known or potential rate of error'; and (4) whether the theory has been generally accepted." *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 686-87 (8th Cir. 2001) (citing *Daubert v. Merrell Dow Pharm.*, 509 U.S. 570, 593-94 (1993)). "*Daubert*'s progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Id.* "[T]he trial court is left with great flexibility in adapting its analysis to fit the facts of each case." *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1082 (8th Cir. 1999).

DISCUSSION

In their motion for reconsideration, Defendants challenge the testimony of Dr. Elghobashi, an engineering expert, and all three medical experts. The Court will address each argument in turn. If the Court grants Defendants' *Daubert* motions, Defendants argue that summary judgment should follow. *See, e.g.*, *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 968 (D. Minn. 2009) (granting summary judgment following the exclusion of plaintiffs' general causation expert). In the alternative, Defendants request that the Court certify the general causation issue under 28 U.S.C. § 1292(b).

The Court has reviewed the arguments made during Defendants' initial *Daubert* motion to exclude Plaintiffs' medical and engineering experts, the experts' testimony during the *Gareis* trial in May 2017, and the new evidence proffered by Defendants in their motion to reconsider. For the following reasons, the Court grants Defendants' *Daubert* motions, and consequently, grants summary judgment in favor of Defendants.

I. DR. ELGHOBASHI'S TESTIMONY

Dr. Elghobashi's testimony relies on a CFD model, which simulated the impact of the Bair Hugger on the dispersion of squames in an OR. The model compared the blower off and on and concluded that operating the Bair Hugger increases the number of squames reaching the surgical site.

Defendants do not dispute Dr. Elghobashi's qualifications. Dr. Elghobashi is a professor at the University of California Irvine Department of Mechanical and Aerospace Engineering and a recognized expert in the field of computational fluid dynamics. Relying on the CFD simulation, Dr. Elghobashi opines that the Bair Hugger disrupts airflow in the OR and causes squames to reach the surgical site.

Plaintiffs' attorneys hired Dr. Elghobashi to create a CFD model to study the interaction between the OR heating ventilation and air conditioning ("HVAC") system and forced-air warming devices to understand the effect of blowing hot air on the dispersion of squames in an OR. A "large-eddy simulation" ("LES") is one of the methods used in computational fluid dynamics simulations. This modeling relies on engineering principles and several governing equations related to fluid dynamics and heat transfer that are solved by super computers. The parties agree, and the Court found in its

December 13th, 2017 order, that the physics underlying Dr. Elghobashi's simulation is reliable.

Dr. Elghobashi retained another CFD expert, Dr. Sourabh Apte, to build the computer simulation using certain inputs provided by Dr. Elghobashi. The LES replicated an OR with an operating table, side tables, surgical lamps, medical staff, and a patient. At trial, Dr. Elghobashi listed a number of key parameters—or "boundary conditions"—that were required to calculate how the squames would move within the OR. Those parameters included the size, number and location of inlet and outlet vents for the HVAC, the volumetric airflow through those vents, the temperature of the air blown into and exiting from the Bair Hugger warming blanket, and the volumetric airflow exiting from the Bair Hugger blower.

He then evaluated the effect of the Bair Hugger on particles—ten microns in size or greater—that are large enough to carry bacteria. His simulation placed three million squames on or within one centimeter of the OR floor near the operating table. He also created four imaginary "boxes" in the simulated airspace at locations representing key areas such as the area where surgical tools are stored and the area of the surgical procedure. The goal of the simulation was to determine if squames lifted into the air by the Bair Hugger reached those areas.

Dr. Elghobashi ran simulations with the Bair Hugger blower off and on. From those simulations, he performed mathematical calculations to project the movement of the squames. The CFD model showed that the warm air from the Bair Hugger disrupts the HVAC airflow and lifts squames into the "imaginary boxes of interest" above the

operating table. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 59. In contrast, when the Bair Hugger is off—and "only the ventilation air from the inlet grilles and thermal plumes created by the warm surfaces including surgical lights, surgeons' heads, patient's head, and patient's knee are responsible for the dispersion of squames"—the model demonstrated that the squames are quickly dispersed to the outlet grilles and no squames enter the imaginary boxes of interest. *Id.* at 57. From these results, Dr. Elghobashi "concluded that without the hot air discharged from the blower, the ventilation air circulation alone cannot disperse the squames to the surgical site." *Id*. Additionally, he observed that "[t]he thermal plumes from various warm surfaces only slightly affect the air coming from the inlet grilles and do not affect the motion of the squames." *Id.*

Defendants argue that Dr. Elghobashi's trial testimony establishes that his CFD model does not support general causation. At trial, Dr. Elghobashi admitted that his simulation does not account for many other sources of turbulence that would be found in any real-world OR, such as the movement of medical personnel. Consequently, Defendants argue that Dr. Elghobashi cannot rely on the CFD results to conclude that the Bair Hugger system would have a similarly meaningful impact in a real OR.

Plaintiffs respond that Dr. Elghobashi explained at trial that these additional variables, if measured, would only exacerbate the Bair Hugger's effect. They contend Dr. Elghobashi, in isolating the Bair Hugger's effect, applied reliable scientific methodology. Further, Plaintiffs assert that any disagreement with "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Bonner*

v. ISP Techs., Inc., 259 F.3d 924, 929 (8th Cir. 2001) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)).

The Court excludes Dr. Elghobashi's testimony for the following reasons. First, Dr. Elghobashi's conclusion relies on an unproven and untested premise. Second, there is too great an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect in the real world. Third, the CFD simulation was developed for litigation, which raises concerns about its reliability and objectivity.

A. There is Too Great an Analytical Gap Between the CFD Results and Dr. Elghobashi's Conclusion About Real-World Effects

Defendants do not challenge the reliability of CFD generally. Rather, Defendants challenge the reliability of the causal inferences that Dr. Elghobashi draws from the CFD model.

The Supreme Court in *Daubert* emphasized that a key consideration in assessing whether scientific knowledge will assist the trier of fact is "whether it can be (and has been) tested." 509 U.S. at 593. Indeed, the Court recognized that "[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified." *Id.*

Applying *Daubert*, the Eighth Circuit affirmed the exclusion of expert testimony where that expert's causation theory relied on "an unproven and indeed untested premise." *Polski v. Quigley Corp.*, 538 F.3d 836, 840 (8th Cir. 2008). In *Polski*, plaintiffs alleged that the use of Cold-Eeze, a nasal spray made for the treatment of cold

symptoms, permanently impaired their senses of taste and smell. *Id.* at 837. Plaintiffs' expert opined that the spray emitted from the Cold-Eeze bottle traveled into the nasal cavity, and caused zinc ions in the spray to come into direct contact with the olfactory epithelium. *Id.* at 839. But the expert never tested this theory, which the district court observed "could have easily and ethically been tested." *Id*. at 840. According to the Eighth Circuit, the district court did not abuse its discretion by concluding that this untested theory was "not sufficiently reliable to be admitted under Rule 702." *Id.* at 839-41 (quoting *Polski v. Quigley Corp.*, No. 04-4199, 2007 WL 2580550, at *5 (D. Minn. Sept. 5, 2007)). The Eighth Circuit explained that plaintiffs had the burden of establishing the testimony's admissibility, which "required sufficient proof that [the expert's] testimony was 'the product of reliable principles and methods,' and that [the expert] 'applied the principles and methods reliably to the facts of the case.'" *Id.* at 841 (quoting Fed. R. Evid. 702).

This case similarly involves an unproven and untested theory. Although Dr. Elghobashi did conduct the CFD modeling, which in broad terms might be considered a "test," he never tested his ultimate conclusion. The CFD model showed that—in a simulated OR—the Bair Hugger increases the number of squames that reach the surgical site. The model also showed that, when the Bair Hugger is off, the squames are quickly dispersed to the outlet grilles and do not reach the surgical site. Relying on the CFD model, Dr. Elghobashi concluded that squames would not reach the surgical site "without the hot air discharged from" the Bair Hugger. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 55.

Both Dr. Elghobashi and plaintiffs' counsel repeatedly emphasize that the simulation is intended to represent what happens in a real-world OR where a knee surgery is being performed. At trial, Dr. Elghobashi testified that the CFD simulation reflects conditions "identical to what happens in reality" because he only omitted "insignificant machines, computers and things which are not really important." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 893:4-8. Plaintiffs' counsel similarly emphasized that the simulation was "not an animation" but "a real world model of what happens based on generally accepted mathematical principles." ECF No. 1000 (Oct. 25, 2017 *Daubert* Hearing Tr.) at 411:8-10.[3]

[3] To the extent Plaintiffs imply that the CFD model reconstructs the particle movement in a surgery where infection occurs, the model is inadmissible for this purpose. Simulations "offered as evidence of what actually happened" are more like "experimental evidence and require a showing of substantial similarity." 5 Christopher B. Mueller & Laird C. Kirkpatrick, Federal Evidence § 9:26 (4th ed. 2019). In the Eighth Circuit, "[a] court may properly admit experimental evidence if the tests were conducted under conditions *substantially similar* to the actual conditions." *Dunn v. Nexgrill Industries, Inc.*, 636 F.3d 1049, 1055 (8th Cir. 2011) (emphasis in original) (quoting *McKnight v. Johnson Controls, Inc.*, 36 F.3d 1396, 1401 (8th Cir. 1994)). The simulated OR in the CFD model falls short of being "substantially similar" to a real-life OR. Moreover, the Court emphasizes that in other accident reconstruction cases where federal courts recognized the reliability of CFD, the experts compared their models to photographs of the accident to support or refute their theory. *See, e.g., Turner v. Liberty Mut. Fire Ins. Co.*, No. 4:07-CV-00163, 2007 WL 2713062, at *3 (N.D. Ohio Sept. 14, 2007) (the expert "compared the results of the simulation to 'physical and eyewitness evidence [photographs] to support or refute the hypothesis'"); *Dejana v. Marine Tech., Inc.*, No, 4:11-cv-1690, 2013 WL 4768407 at *9-12 (E.D. Mo. Dec. 20, 2013) (the expert compared the results to photographs of the accident). Consequently, the Court's subsequent analysis focuses on the admissibility of the CFD model for the purpose of predicting the movement of airflow in a theoretical surgery based on mathematical equations. In this context, "[i]t is essential that the model be based on assumptions and data that are consistent with the evidence in the case rather than on speculation." Mueller & Kirkpatrick, Federal Evidence § 9:26.

However, at trial, Dr, Elghobashi testified that the simulated OR omitted other sources of heat and air movement.[4] Most notably, the simulated OR does not account for the movement of personnel, which has a significant impact on airflow disruption. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 961:7-962:1. For example, in his expert report, Dr. Elghobashi discussed the Chow & Wang (2012) study, which—using Reynolds-averaged Navier Stokes ("RANS") modeling[5]—found that the periodic bending movement of one surgeon increased the concentration of particles to a larger-than-recommended value near the surgical site. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 4-5. Further, at trial, Dr. Elghobashi cautioned that turbulent flow cannot be measured by hand because even reaching a hand in "would be invasive to the flow" and "interrupt the results." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 895:14-21. For this reason, Dr. Elghobashi explained that scientists measure turbulent flows with "noninvasive means" such as laser beams. *Id.*

Despite meaningful differences between the CFD simulation and the real world, Dr. Elghobashi made no attempt to limit his testimony about the Bair Hugger's effect to

[4] Dr. Elghobashi's published study similarly acknowledged that there are "several other complexities involving other medical equipment in an OR, motion of the medical staff, opening and closing of the OR door, among others are not accounted for." ECF No. 1813-30, PX36 (He 2018) at 19. While the study suggests that "these complexities may not impact the main conclusions of the present study," the study provides no support for this statement. *Id.* Here, the Court cites to Dr. Elghobashi's submission for publication, which Plaintiffs attached to their briefing. At trial, Dr. Elghobashi confirmed that this study was published in January 2018. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 863:22-865:7; 929:2-6.

[5] Dr. Elghobashi accepts the validity of RANS modeling but considers LES simulations to be superior.

ORs without these other sources of turbulence.[6] Instead, he concluded that the Bair Hugger's effect on the dispersion of squames would be *exaggerated* in a real-world OR. Yet, this hypothesis was never tested. Because Dr. Elghobashi never factored in other sources of heat and air movement, the CFD model did not test whether squames would be able to reach the surgical site without the hot air discharged from the blower in a real OR. The model also did not test whether squames would be significantly more likely to reach the surgical site when the Bair Hugger is turned on in a real OR. Thus, applying *Polski*, the Court finds that Dr. Elghobashi's conclusion relies on an unproven and untested premise.[7] Dr. Elghobashi's failure to test his theory "undermines the reliability of [his] opinion and renders it too speculative to admit." *See Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1061-63 (D. Minn. 2012) (excluding expert opinions where the experts "never attempted to validate their theory . . . they simply theorized that this might have happened").

[6] Dr. Elghobashi's testimony might be admissible, if relevant, had he limited his conclusion to basic principles of thermodynamics—such as the conclusion that the Bair Hugger may cause particles to rise by blowing hot air. *McKnight*, 36 F.3d 1396 at 1401 (citing *Champeau v. Fruehauf Corp.*, 814 F.2d 1271, 1278 (8th Cir. 1987)) ("[W]here the experimental tests do not purport to recreate the accident, but instead the experiments are used to demonstrate only general scientific principles, the requirement of substantially similar circumstances no longer applies.").

[7] Plaintiffs argue that *Daubert* does not require testing, only testability. For support, Plaintiffs cite *Holverson v. ThyssenKrupp Elevator Corp*, Civ. No. 12-2765, 2014 WL 3573630 at *9 (D. Minn. July 18, 2014) in which the court allowed expert evidence despite the expert's failure to test his theory of liability. However, the court justified its decision by emphasizing that although the expert did not test his theory, it was corroborated by several real-world facts. *Id.* That is not the case here.

The Court also finds *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016) instructive. In *In re Mirena*, the plaintiffs argued that the Mirena, an intrauterine device, perforated the plaintiffs' uteruses. *Id.* at 407. Dr. Jarrell, a biomedical engineer, opined that although the Mirena generally has flexible arms, these arms become stiff and rigid when loaded in "constrained conditions" sometimes causing perforation. *Id.* at 438. To test his theory, Dr. Jarrell applied double-sided tape to the device's arms to apply pressure in order to mimic a constrained condition. *Id.* at 441. He then measured the force that the device transferred to uterine tissue. *Id.* However, Dr. Jarrell admitted at his deposition that "he did not have any basis to suggest that the way the Mirena became rigid in his experiment [with double-sided tape] occurs *in vivo* (inside a human being)." *Id.* For this reason, the court found that these testing conditions did not "reliably replicate the conditions inside a woman's uterus, and therefore render[ed] his methodology and the conclusions he draws from it unreliable." *Id.* Accordingly, the court concluded that the differences between the testing conditions and the real world creates "too great an analytical gap between the data and the opinion proffered." *Id.* at 442 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Here, too, there is an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect. Dr. Elghobashi contends that he did not include other sources of turbulence in order to "isolate the effect of the Bair Hugger" because "that's how we do science." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 963:1-5. But in trying to isolate the Bair Hugger, Dr. Elghobashi's simulation misleadingly implies that the Bair

Hugger system is the only variable in the OR, and that squames could not reach the surgical site without the Bair Hugger operating. Such an extrapolation contradicts Dr. Elghobashi's acknowledgement that the movement of personnel meaningfully impacts turbulent airflow.[8] Based on the CFD model alone, Dr. Elghobashi does "not have any basis" to suggest that squames would only reach the surgical site when the Bair Hugger is blowing in a real OR. *Cf. In re Mirena*, 169 F. Supp. 3d at 441.

Dr. Elghobashi also speculates about the Bair Hugger's effect in a real OR. Dr. Elghobashi, without support,[9] emphasizes that his model was the "best case scenario for 3M" because introducing other sources of turbulence, such as the surgical team's movement, would only have enhanced the dispersion of squames and increased the Bair Hugger's effect. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 917:13-15. But "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. Dr. Elghobashi has not cited any study that factors in other sources of turbulence and reaches a similar conclusion. Nor has he tested this theory even though such tests are feasible.[10] Thus, his conclusion that the Bair Hugger

[8] As discussed below, other researchers have emphasized that "[t]he primary source of these airborne microorganisms is the people in the operating room, such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)." ECF No. 1813-32, PX38 (Darouiche 2017) at 2.

[9] At trial, Dr. Elghobashi stated: "I know that based on my knowledge . . . [w]e gave you the best case scenario, trust me about this, trust me." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 917:13-15.

[10] Although Dr. Elghobashi's CFD code had been validated, he made no attempt to validate his CFD simulation with experimental evidence. Dr. Elghobashi admitted in his published study there are "a lack of detailed experimental measurements . . . in an OR

significantly impacts the trajectories of squames in a real-world OR, ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 63-64, is nothing more than his say-so.

To be sure, expert testimony inherently involves some amount of educated guesswork: "A certain amount of speculation is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003). Dr. Elghobashi's attempted gap-filling is more like a leap of faith than an inferential leap. Dr. Elghobashi's model implies that the Bair Hugger is the but-for cause of squames reaching the surgical site in the simulated OR. And he assumes that a real OR would amplify the Bair Hugger's effect. At the same time, he conceded at trial that other factors exist in a real OR that significantly impact airflow and the trajectories of squames. Because his simulation never factors in these other sources of turbulence, it cannot answer important questions, such as: (1) in a real OR, can these other sources of

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during a clinical trial" that would "help validate the numerical predictions." ECF No. 1813-30, PX36 (He 2018) at 19. He acknowledged that "such detailed data during a clinical trial are potentially feasible but may cost up to $ 2 M." *Id.* For support for this cost estimate, Dr. Elghobashi cites a "private communication." *Id.* at 21. Dr. Elghobashi also testified that he could have simulated personnel movement, but he was not asked to. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 918:1-8. While Dr. Elghobashi only ran two simulations with the constraints discussed above, the Court emphasizes that in other cases where federal courts recognized the reliability of CFD in litigation, the experts based their conclusions on comparisons between several simulations. *See, e.g., Quiet Technology DC-8 v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1338 (11th Cir. 2003) (the expert relied on 16 simulations); *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1217-21 (Fed. Cir. 2006) (the expert relied on 40 to 50 iterations of the simulation); *Dejana*, 2013 WL 4768407 at *9-12 (the expert performed more than 100 CFD simulations of a boat operating at different speeds to determine at what speed the predicted damage matched the actual photos of damage).

turbulence carry squames to the surgical site without the Bair Hugger?; (2) if they can, does the number of squames reaching the surgical site increase when the Bair Hugger is turned on?; and (3) how would the non-Bair Hugger created turbulence interact with or affect the Bair Hugger-generated eddies? Dr. Elghobashi never attempts to answer these questions and bridge the gap in his analysis. Instead, he simply assumes that the Bair Hugger significantly increases the number of squames reaching the surgical site in a real OR. Such speculation renders his methodology and the conclusions he draws from it unreliable.

Plaintiffs argue that, as a general rule, any disagreement with "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Bonner*, 259 F.3d at 929 (quoting *Hose*, 70 F.3d at 974). Plaintiffs are correct that a dispute solely over inputs, such as the Bair Hugger's air temperature, might not render Dr. Elghobashi's testimony inadmissible.[11] *See, e.g., In re Zurn Pex Plumbing Prod. Liab. Litig.*, 644 F.3d

[11] The CFD model was limited to specific boundary conditions, such as number and placement of vents and the temperature of the air exiting the Bair Hugger. At trial, Dr. Elghobashi admitted that adjusting any inputs would alter the results, which is why "prescribing correct boundary conditions is crucial to predicting a given flow." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 862:14-18. Consequently, if any inputs differ in the real world or from OR to OR, then the simulation results may not useful to the fact finder in those cases. *Cf. Lauzon*, 270 F.3d at 687 (analyzing, under *Daubert*'s relevance factor, "whether the proposed expert sufficiently connected the proposed testimony with the facts of the case"). For instance, Defendants argue that their expert, "who took actual measurements of the temperature of the air exiting a Bair Hugger blanket, could not replicate Dr. Elghobashi's assumption of 106°F (41.11°C)—after measuring several areas of the blanket, the highest average temperature [] recorded was 36°C." ECF No. 805 (Mem. in Supp. of Defs.' 2017 Mot. to Exclude Engineering Experts) at 43. In its December 13th, 2017 order, however, the Court found that the simulation's inputs were not so fundamentally unsupported that they could offer no assistance to the jury.

604, 614 (8th Cir. 2011) ("A district court necessarily has 'considerable discretion' in deciding whether to admit expert testimony where the factual basis is disputed."); *Quiet Tech*, 326 F.3d at 1343-44 (admitting CFD model of jet engine over challenge to expert's inputs and equations).

But, here, Plaintiffs have held out the CFD simulation as representing a real-world OR even though there are meaningful differences. This is not a mere quibble over whether there are three doctors versus four, whether the OR doors were opened once or several times, or whether the OR dimensions vary slightly. Dr. Elghobashi's conclusions have drifted from the factual realities of his test. *Bonner*, 259 F.3d at 929-30 (quoting *Hose*, 70 F.3d at 974) (recognizing that courts must exclude expert testimony where it is "so fundamentally unsupported that it can offer no assistance to the jury"). "[C]ourts retain broad discretion under Rule 403 to exclude computer animations or simulations, particularly where they are based on questionable assumptions or project such a slanted or distorted view of the evidence as to be unfairly prejudicial or misleading." Mueller & Kirkpatrick, Federal Evidence § 9:26. Dr. Elghobashi's testimony is not saved from exclusion simply because he initially applied reliable physics principles.[12]

[12] Even if the Court limited Dr. Elghobashi's testimony to the effect of the Bair Hugger in a quiet OR where no surgery is being performed, this limited testimony would not assist the trier of fact in resolving the factual dispute. In every case in this MDL, Plaintiffs will ultimately have to prove that their infection would not have occurred but for the use of the Bair Hugger system, or that the Bair Hugger system was a substantial contributing cause. Elghobashi's CFD simulation does not allow for any real-world comparison between an OR with a Bair Hugger and an OR without a Bair Hugger.

This decision "does not mean that [Dr. Elghobashi's] theory is necessarily *wrong*; it simply means that the theory meets none of the indicia of reliability identified in *Daubert* and therefore must be excluded." *Polski*, 538 F.3d at 841 (emphasis in original) (quoting *Polski*, 2007 WL 2580550, at *5). For these reasons, Dr. Elghobashi's testimony is not sufficiently reliable and too speculative to be presented to the jury.

B. Dr. Elghobashi Developed the CFD Model During Litigation

Additionally, Dr. Elghobashi's testimony and CFD model were "developed for litigation." *Lauzon*, 270 F.3d at 687. At trial, Dr. Elghobashi testified that Plaintiffs' counsel hired him in April 2016 to conduct a CFD simulation relating to issues in this litigation. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 923:8-12. Prior to his involvement in this litigation, he had never conducted a CFD model involving a medical device or an OR. *Id.* at 933:7-20. Because Dr. Elghobashi had never observed a Bair Hugger in an OR, the plaintiffs' lawyers joined Dr. Elghobashi on a visit to an OR room, where one lawyer pretended to be the patient on the operating table as no actual surgery was taking place. *Id.* at 954:24-955:17.

"[I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). When an experts' findings are developed in the course of litigation, courts have raised concerns about the objectivity and reliability of the findings as well as the possibility that the parties have "shop[ped] for experts who will come to the desired conclusion." *Id.* These same concerns exist here. For instance, plaintiffs' lawyers

accompanied Dr. Elghobashi on his one and only visit to an OR. Dr. Elghobashi also took minimal measurements for the model's inputs. Instead, he relied on materials provided by the plaintiffs' attorneys. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 947:18-25.

Plaintiffs defend Dr. Elghobashi's study because it is peer-reviewed and published. But the published study discloses significant conflicts of interest.[13] While the study's publication indicates that other scientists think it has scientific value, this does not guarantee that the conclusions reached are reliable.

For these reasons, the Court excludes Dr. Elghobashi's testimony.

II. MEDICAL EXPERTS

The medical experts rely on a number of non-epidemiological studies and Dr. Elghobashi's CFD model, which together describe the mechanism by which the Bair Hugger transmits contaminated airborne particles into the sterile surgical site. They also cite the McGovern Observational Study ("Observational Study"), an epidemiological study, which found a statistically significant association between the Bair Hugger and infection.

[13] In the published study, the authors originally declared no conflicts of interest. ECF No. 1813-30, PX36 (He 2018) at 19. But at trial, Dr. Elghobashi admitted that the editors subsequently added the following disclosure: "Dr. Elghobashi is a testifying witness in a court case against 3M, in which the plaintiffs urge that the Bair Hugger patient warming system causes periprosthetic joint infections by disrupting the airflow in ORs. Dr. Apte is a paid consultant for the plaintiffs." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 929:3-931:4.

Defendants do not dispute the experts' qualifications. Dr. Jarvis is a medical doctor with experience in infectious disease, healthcare epidemiology, and infection control. He formerly worked at the Center for Disease Control with a focus on infectious diseases associated with healthcare. Dr. Samet is a medical doctor with a master's degree in epidemiology from the Harvard School of Public Health. His research focuses on the health consequences of inhaled agents, including tobacco and radon, and is known for his work as the plaintiffs' expert in the tobacco litigation. Dr. Stonnington, an orthopedic surgeon in Mississippi, relies on his seventeen years of clinical experience.

Defendants argue that: (1) the Court's order in *Gareis* that excluded Plaintiffs' "dirty machine" theory should apply to the entire MDL; (2) the Jeans (2018) study demonstrates that the Observational Study is unreliable; and (3) the consensus at the 2018 International Consensus Meeting ("ICM") on Musculoskeletal Infection reinforces that Plaintiffs' medical experts have made an improper inference regarding causation.

Plaintiffs respond that the Observational Study is relevant and reliable evidence of general causation—notwithstanding the Jeans (2018) study—and that the 2018 ICM does not preclude expert opinions on causation. Additionally, Plaintiffs contend that the Court's ruling in *Gareis* about the "dirty machine" theory should not apply to the entire MDL.

The Court finds that Plaintiffs' medical expert opinions are unreliable and should be excluded under *Daubert* because: (1) there is too great an analytical gap between the literature and the experts' general causation opinions; (2) the experts failed to consider

obvious alternative explanations; and (3) the causal inferences made by the experts have not been generally accepted by the scientific community.

A. There is Too Great an Analytical Gap Between the Scientific Literature and the General Causation Opinions of Plaintiffs' Medical Experts

The state of the scientific literature presents a challenge for the general causation experts. No medical organization, regulator, or peer-reviewed study has found that the Bair Hugger causes PJI. Moreover, the only epidemiological study on which the experts rely has expressly disclaimed causation and acknowledged potential confounders. Still, each of plaintiffs' three medical experts reach this conclusion in their reports. None has done so through an experiment, laboratory work, or a new epidemiological study of his own. Drs. Jarvis and Samet arrive at this conclusion by drawing upon the existing literature as well as Dr. Elghobashi's CFD model. Dr. Stonnington relies on his medical training, education, and knowledge, as well as his clinical experience,[14] and to a lesser

[14] Dr. Stonnington's anecdotes from his own practice, on their own, are insufficient to establish causation. In *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001), the Eighth Circuit warned that "[c]ausal attribution based on case studies must be regarded with caution." The Court acknowledged that "[c]ase reports make little attempt to screen out alternative causes . . . [a]nd they often omit relevant facts about the patient's condition." *Id.* at 989-90 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 475 (3d ed. 2011)). As an initial matter, the Court finds that Dr. Stonnington's anecdotal evidence may even be less reliable than the case reports at issue in *Glastetter*. That is because Dr. Stonnington admitted during the *Gareis* trial that, apart from his opinion in the *Gareis* case, he never recorded in a patient's medical record or told a patient that the Bair Hugger caused his or her infection. *Gareis* 16-cv-4187, ECF No. 471 (May 16, 2018 Trial Tr.) at 425:18-25. Moreover, Dr. Stonnington's anecdotal reports do not include basic numerical data or years when infections occurred.

extent, the scientific literature. Plaintiffs emphasize that the experts have relied on the totality of the evidence to draw this conclusion.

The Supreme Court established that a court may exclude expert testimony where there is "too great an analytical gap between" the underlying evidence and the expert's opinion. *Joiner*, 522 U.S. at 146. In *Joiner*, the plaintiff alleged that his exposure to polychlorinated biphenyls ("PCB") as an electrician "promoted" his cancer. *Id.* at 139-40. According to the Supreme Court, the district court did not abuse its discretion when it excluded expert testimony because the experts had relied on four epidemiological studies that were "not a sufficient basis" for their conclusion that exposure to PCB caused cancer. *Id.* at 145. To support its holding, the district court analyzed the limits of each study. For example, the district court noted that one study observed a statistically significant association but involved a number of confounding variables. *Id.* at 146.

The Eighth Circuit similarly affirmed the district court's exclusion of expert testimony where the medical texts underlying an expert's report failed to present persuasive scientific evidence of causation. In *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 988-90 (8th Cir. 2001), the Eighth Circuit considered whether plaintiff's experts had articulated a theory to explain how Parlodel, a medication, caused an intracerebral hemorrhage (ICH) in the plaintiff's brain. The experts had theorized that Parlodel causes arteries to constrict—known as vasoconstriction—resulting in elevated blood pressure, which in turn is a risk factor for ICHs. *Id.* at 989. However, the Eighth Circuit agreed with the district court that the evidence underlying the expert's theory "does not demonstrate to an acceptable degree of medical certainty that Parlodel can

cause an ICH." *Id.* The court analyzed several medical texts that the experts relied on, noting that "[a]t least one text ventured a hesitant conclusion that Parlodel causes vasoconstriction, but the explanation made clear that more research was needed before causation could be firmly established." *Id.* at 990. The court concluded that "these texts do not present persuasive scientific evidence that Parlodel causes vasoconstriction." *Id.*

Plaintiffs contend that proponents of expert testimony need not prove that the conclusions are correct, and courts must not determine which of several theories has the best provenance. *Kuhn v. Wyeth*, 686 F.3d 618, 625 (8th Cir. 2012); *see also Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014) ("[D]istrict courts are admonished not to weigh or assess the correctness of competing expert opinions."). This does not mean, however, that an expert's conclusions are off limits. In *Joiner*, the Supreme Court clarified that "conclusions and methodology are not entirely distinct from one another" and "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S. at 146. The Court concluded that it was "within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions." *Id.* at 146-47. Consequently, it is within the Court's discretion to review the studies underlying an expert's report and to find that the expert's conclusion is not supported by the totality of the evidence. The Court does so below.

1. The "Dirty Machine" Theory

Plaintiffs' first theory of causation is that the Bair Hugger, lacking an adequate filtration system, emits contaminants into the OR, and thus increases the bacterial load reaching the surgical site. In May 2018, in response to a motion in limine, the Court excluded evidence supporting this theory from the *Gareis* trial, finding that Plaintiffs lacked any scientific evidence to support it. *Gareis* 16-cv-4187, ECF No. 306 (Order re Mot. in Lim.) at 2 ("Plaintiffs have no evidence that anyone has caught colony-forming units of bacteria floating out of the blanket's perforations.").[15] Defendants argue that because this ruling did not depend on any case-specific facts in *Gareis*, this ruling should apply to the entire MDL.

Plaintiffs respond that the Court's decision depended on the lack of evidentiary support in Dr. Jarvis's specific causation opinion but contend that the medical experts' general causation reports nevertheless support this theory. For example, Drs. Jarvis and Stonnington cite several studies like Avidan (1997), Albrecht (2009) and (2011), and Reed (2013), which found that the Bair Hugger internally generates and then emits contaminated particles out of the distal hose. Drs. Jarvis and Stonnington then conclude that because the devices emit contaminated air, these devices increase the risk of infection. ECF No. 1813-1, PX1 (Jarvis Rpt.) at 10-11; ECF No. 1813-3, PX3 (Stonnington Rpt.) at 6-7. Dr. Samet, citing evidence summarized by Dr. Jarvis,

[15] The parties' experts disagree about whether the Bair Hugger blanket may act as a filter.

similarly concludes that the Bair Hugger "could increase the dose of organisms delivered to the surgical site." ECF No. 1813-2, PX2 (Samet Rpt.) at 17.

The Court finds that there is too great an analytical gap between the experts' conclusions and the scientific literature summarized in their reports. In reaching these conclusions, the experts ignore the underlying studies' limitations. For example, these studies support a conclusion that the Bair Hugger emits contaminated air out of the distal hose. But no study even considered whether contaminated air emitted from the hose could reach the surgical site and cause infection.[16] Both Albrecht studies clarify that the researchers did not evaluate or establish a direct link between forced-air warming and increased surgical site infection rates. ECF No. 750 (Mem. in Supp. of Defs.' 2017 Mot. to Exclude General Causation Medical Experts) at 25. Additionally, Reed (2013)—the most recent study cited by the experts in support for this theory—explicitly rejected finding a direct link between the Bair Hugger's contaminated air and infection because it is "presently unknown" whether the contaminated air would reach the surgical site. ECF No. 950-20, PX30 (Reed 2013) at 6. Because Plaintiffs' medical experts do not cite any studies after Reed (2013), the Court finds no support for their conclusion that the contaminated emissions reach the surgical site.

[16] Because the patient's torso and the Bair Hugger blanket are covered with surgical draping, the warm air does not blow directly onto the lower body surgical site. (In upper body surgeries, like shoulder surgeries, the blanket is placed over the lower half of the patient's body.)

Perhaps the experts assume that this contaminated air reaches the surgical site via the "airflow disruption" theory. But as discussed below, the studies underlying this theory also do not establish that the Bair Hugger causes infection.

2. The "Airflow Disruption" Theory

At the *Gareis* trial, Plaintiffs and their medical experts articulated their second theory of causation—the "airflow disruption" theory—as follows: HVAC systems in ORs create a "forcefield" around the surgical site by pushing particles down to the floor where vents take those particles, including any bacteria, out of the room. However, when the Bair Hugger is turned on, hot air escapes from the Bair Hugger blanket and the bottom edge of the surgical draping, rises, and then disrupts the protective "forcefield." This in turn causes squames (sometimes referred to as colony forming units ("CFUs")) to float into the surgical site.

The experts rely on two bodies of supporting evidence: empirical studies that examine air flow patterns in ORs and Dr. Elghobashi's testimony and CFD simulation. Defendants challenge both lines of evidence. Defendants contend that the empirical studies do not reflect real-world conditions and thus, standing alone without Dr. Elghobashi's CFD model, do not provide sufficient support to infer general causation.

Reliance on Empirical Studies

Plaintiffs assert that several empirical studies have found that the convection currents produced by the Bair Hugger significantly increase the number of particles in the

sterile field.[17] Plaintiffs concede that these studies do not involve real ORs, but argue that it would be an abuse of discretion for the Court to require the experts to rely only on studies that perfectly reflect the real world. Plaintiffs contend that as long as the methods employed by the expert are scientifically valid, "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony." *Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017) (quoting *SEC v. Das*, 723 F.3d 943, 950 (8th Cir. 2013)). The Court agrees that these peer-reviewed studies are not so unreliable that they should be excluded from the evidence. Rather, for the following reasons, the Court finds that there is too great an analytical gap between these studies and the experts' conclusion that the Bair Hugger causes infection.

Plaintiffs' experts piece together an array of studies to ultimately conclude that the Bair Hugger causes PJI. First, the experts contend that the Bair Hugger increases the number of particles over the surgical site. While these studies demonstrate that forced-air warming devices can increase particle counts over the surgical site under certain conditions, they do not conclude that this same increase exists in the real world. For example, all three experts rely on the Legg studies, which found increased particle counts over the surgical site associated with the use of the Bair Hugger. Yet, these studies explicitly limit their findings to their exact operating theater set up. ECF No. 1813-16, PX21 (Legg 2012) at 4; ECF No. 1813-17, PX22 (Legg 2013) at 5. Moreover, in the

[17] *See, e.g.*, ECF No. 1813-16, PX21 (Legg 2012); ECF No. 1813-17, PX22 (Legg 2013); ECF No. 1813-18, PX23 (Belani 2012); ECF No. 1813-19, PX24 (Dasari 2012); ECF No. 1813-20, PX25 (McGovern 2011).

2013 study, the authors acknowledge that "[t]his study does not show that forced-air warming increases the risk of infection." ECF No. 1813-17, PX22 (Legg 2013) at 5. Additionally, Drs. Jarvis and Samet cite the Dasari (2012) study, which measured temperatures in an OR around a draped mannequin and found that the Bair Hugger significantly elevated mean temperatures over the surgical site. The authors limited their conclusions, however, to the study set up and cautioned that "the definitive effects of this excess heat on clinical outcomes are presently unknown." ECF No. 1813-19, PX24 (Dasari 2012) at 6. Lastly, all three experts cite the Belani (2013) study, which used bubbles to investigate the effect of forced-air warming on OR airflow and found that the forced-air warming significantly disrupted airflow and increased bubble counts over the surgical site.[18] These researchers also cautioned that their conclusions were based on the study's "exact setup" and that the researchers were "unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery." ECF No. 1813-18, PX23 (Belani 2013) at 6.

Furthermore, these studies only consider particle counts, and not whether forced-air devices increase infection. Attempting to close the analytical gap between increased particle counts and infection, the experts cite several studies linking higher particle counts at the surgical site with increased risk of infection. For example, all three experts cite the Stocks (2010) study, which found a correlation between the number of airborne

[18] The McGovern (2011) study includes both an observational study, discussed in detail below, and a "bubble" experiment with similar findings to the Belani study. ECF No. 1813-20, PX25 (McGovern 2011) at 6.

particles equal or greater than ten microns in size and the number of CFUs. ECF No. 1813-33, PX39 (Stocks 2010) at 6.

Dr. Jarvis's trial testimony, however, exposed that the Stocks study cannot bridge this gap. At trial, Dr. Jarvis testified that particle size matters because no study has found that smaller particles can carry bacteria. *Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 759:17-760:19. Dr. Jarvis also admitted that there is no study that shows that the Bair Hugger has any impact on particles that are large enough to carry bacteria other than the "CFD models perhaps." *Id.* at 761:5-8. Consequently, Dr. Jarvis conceded that no study has found that the Bair Hugger increases the number of *bacteria* arriving at the surgical site. *Id.* at 768:23-769:1.

The experts also cite a randomized controlled study, Darouiche (2017), which found a correlation between reducing CFUs at the surgical site and lower rates of infection. But this study also fails to close this gap. First, the researchers did not even study forced-air warming devices. The study involved the Air Barrier System, which passes ambient air through a filter at the surgical site. Second, this study recognized that "[t]he primary source of these airborne microorganisms is the people in the OR, such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)." ECF No. 1813-32, PX38 (Darouiche 2017) at 2. Thus, this study lends support for the theory that personnel movement in the OR is a

major risk factor of infection[19]—a factor not reflected in Dr. Elghobashi's simulation or the studies described above.[20] Therefore, as a whole, these studies are too far removed from the conditions of real ORs to support Plaintiffs' experts' conclusion that the Bair Hugger system causes infection in real-world operations.

Reliance on Dr. Elghobashi's CFD Model

Given the gap in the scientific literature discussed above, Dr. Elghobashi's CFD model plays an essential role in understanding the impact of the Bair Hugger on larger particles that carry bacteria. *See Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 763:18-23 (Dr. Jarvis testifying that "that's where Dr. Elghobashi in his model can help fill in that gap, where the studies haven't been done"). As Dr. Jarvis acknowledged at trial, the CFD simulation is the only study that even considered the impact of the Bair Hugger on particles ten microns in size. *Id.* at 761:5-8; 807:5-12. Dr. Jarvis also testified that "we have a variety of studies that answer each one of these questions, and when you put [the studies] all together, you get a picture similar to what Dr. Elghobashi has shown with his CFD model that illustrates why the Bair Hugger will increase the risk of prosthetic joint infections." *Gareis* 16-cv-4187, ECF No. 472 (May 17, 2018 Trial Tr.) at 631:6-10.

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[19] Dr. Jarvis also testified at trial that personnel movement has the greatest impact on ten-micron particles. *Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 752:18-753:5.

[20] ECF No. 1813-16, PX21 (Legg 2012) at 3 (single surgeon with no nurse or assistants); ECF No. 1813-17, PX22 (Legg 2013) at 2 (single surgeon); ECF No. 1813-18, PX23 (Belani 2013) at 3 (single anesthetist stood motionless at the head of the table); ECF No. 1813-19, PX24 (Dasari 2012) at 6 (two people walked around); ECF No. 1813-20, PX25 (McGovern 2011) at 3 (surgeon and anesthetist stood motionless).

But even if the CFD model were admissible, there is too great an analytical gap between the CFD results and the medical experts' conclusion that the Bair Hugger causes infection. *See, e.g.*, *In re Mirena IUD*, 169 F. Supp. 3d at 441 (excluding a general causation expert's opinion as unreliable because it was based on a lab test using "equipment apparently intended to mimic the uterus" but that admittedly "[did] not reliably replicate the conditions inside a woman's uterus"). Drs. Jarvis and Samet rely on the simulated off-and-on comparison as evidence that the Bair Hugger disrupts the airflow, brings contaminants from the floor area into the sterile surgical field, and increases the risk of infection in a real-world OR. But, as discussed above, Dr. Elghobashi's simulation does not reflect many sources of turbulence and particles that one would expect in a real OR.

Remarkably, the experts fail to acknowledge these differences, let alone explain how these differences might impact their analysis. Neither expert, for instance, acknowledges the surgical team's movements—one key difference between the CFD model and a real OR. As discussed above, personnel movement in the OR is a major risk factor of infection. As a result, the CFD model—which does not simulate the surgical team's movement—cannot be relied on to establish that the Bair Hugger significantly increases the number of contaminated particles at the surgical site in the real world. Consequently, the experts make too great an inferential leap in their conclusions.

Furthermore, even if Drs. Samet and Jarvis had addressed these differences, they would not have been qualified to fill this analytical gap. It is outside their expertise to opine on how atmospheric eddies are impacted by the Bair Hugger in a real OR as

opposed to in a simulated OR. Perhaps Drs. Samet and Jarvis rely on Dr. Elghobashi's caveat at the end of his report that the inclusion of personnel movement and additional squames in the simulation would only further increase the probability that squames would travel to the surgical site. But as discussed above, Dr. Elghobashi's assumption is problematic as it has not been tested. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

3. The Observational Study

In addition to the mechanistic evidence describe above, the medical experts also rely on epidemiological evidence. Specifically, Plaintiffs' medical experts cite one epidemiological study, the McGovern (2011) Observational Study ("Observational Study"), to show a real-world association between the Bair Hugger and PJI.

Epidemiology is the "statistical study of disease or injury in human populations." Federal Judicial Center, *Reference Manual on Scientific Evidence* 286 (3d ed. 2011). According to the *Reference Manual on Scientific Evidence*, "[e]pidemiology focuses on the question of general causation" by identifying agents that are "associated with an increased risk of disease in groups of individuals." *Id.* at 552. However, "[a]n association identified in an epidemiologic study may or may not be causal." *Id.* at 552-53. Because all studies have flaws, "[i]n evaluating epidemiologic evidence, the key questions, then, are the extent to which a study's limitations compromise its findings and permit inferences about causation." *Id.* at 553.

The Observational Study found a statistically significant association between the Bair Hugger and infection.[21] The Observational Study was an epidemiological study that compared infection rates at Wansbeck Hospital in Northumbria, England, during a period when the Bair Hugger and a period when a conductive warming device were in use. The researchers reviewed infection data to determine whether joint infection rates were associated with the type of patient warming device that was used. It was an observational study, meaning that it was not blinded and controlled like a clinical study.

The study authors warned against conflating correlation with causation: "[t]his study does not establish a causal basis . . . the data are observational and may be confounded by other infection control measures instituted at the hospital." ECF No. 1813-20, PX25 (McGovern 2011) at 8. Further, the authors expressly acknowledged that there was a period when different anti-thrombotic and different prophylactic antibiotic drugs were being used with the two groups of patients. *Id.* Finally, the authors noted that they were "unable to consider all factors that have been associated with SSI, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record." *Id.*

Defendants first argue that the Observational Study is so unreliable that it should be excluded. The Court disagrees. The study is reliable as it is published and peer reviewed. And, even if the study has certain limitations, those limitations could be

[21] The parties dispute, however, if tabulation errors exist in the Observational Study that would impact the statistical significance of the association.

presented to a jury. *Kuhn*, 686 F.3d at 632 (holding that the expert's "reliance on the studies may be tested through the traditional means of cross examination and presentation of contrary evidence").

Nevertheless, as outlined above, it is unreliable for an expert to rely on studies to support conclusions that the study authors were themselves unwilling to reach. *See Joiner*, 522 U.S. at 145-46; *see also Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009) ("It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven."). *Joiner* and *Glastetter* focused on whether the underlying studies provide a sufficient basis for an experts' causation opinions, but district courts have also analyzed whether an expert addresses a study's limitations as a way of determining if the study reliably supports a causation opinion. For example, in *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 277 (S.D.N.Y. 2018), a district court found that an expert "fail[ed] to consider the alternative, and benign, explanations that that study identified for the correlation it found between Mirena and IIH." The court determined that the report "pays only lip service" to the study's "caveat about confounders" as "[i]t nowhere reveals that the [epidemiological] study had not controlled for obesity or recent weight gain." *Id.* at 277-78. Consequently, the court found that the report inappropriately treated the correlation as "affirmative evidence of causation" and excluded the expert's testimony because it did not meet the standards for reliability articulated in *Daubert*. *Id.* at 278.

Here, too, the experts fail to address the McGovern researchers' caveats about confounders and alternative explanations, and thus, they inappropriately treat the association as affirmative evidence of causation. Both Drs. Jarvis and Stonnington cite the Observational Study without discussing the study's limitations and possible confounders. And although Dr. Samet mentions potential confounders acknowledged by the study authors, his description of them is misleading. Dr. Samet states that the Observational Study "has been criticized as potentially reflecting confounding by the non-comparability of prophylactic antibiotic use and thromboprophylaxis in the two periods." ECF No. 1813-2, PX2 (Samet Rpt.) at 12. He likens these criticisms "to the strategies employed for decades by the tobacco industry." *Id.* But by framing these criticisms as disingenuous, he aims to dismiss potential confounders without seriously considering them.

Additionally, Dr. Samet departs from his own description of reliable methodology when opining about causation. *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 448 (8th Cir. 2010) (affirming the district court's holding that the expert's "failure to follow his own general practice . . . created 'too great an analytical gap' between his opinion and the data on which it relied"). Dr. Samet applies several criteria to determine if causation exists. With regard to "strength of association," Dr. Samet reports that the Observational Study establishes "a statistically significant association unlikely to be explained by confounding or other bias." ECF No. 1813-2, PX2 (Samet Rpt.) at 16. Next, Dr. Samet applies the criteria of consistency. Dr. Samet acknowledges, however, that this factor is not applicable to the Observational Study since this factor is generally related to the "findings

of multiple observational studies." *Id.* Instead, Dr. Samet points to the series of empirical studies, which as discussed above, found that the Bair Hugger's convection currents increase the number of particles in the sterile field. But these studies do not establish—let alone consider—whether there was an association between the Bair Hugger and infection.

Without further explanation of Dr. Samet's thought process and how he weighed these criteria, the Court is left to guess why Dr. Samet finds that the consistency factor is met despite conceding that "[t]he McGovern paper supplies the only estimate of the risk" and absent that estimate he "would not be able to judge the quantitative magnitude of the association." ECF No. 1720-1, DX25 (Aug. 8, 2017 Samet Dep.) at 282:16-283:20. Dr. Samet's application of the factors does not reassure the Court that he has bridged the gap between the scientific literature and his causation opinion.[22] *See In re Mirena (No. II)*, 341 F. Supp. 3d at 247 (collecting cases) ("As courts have recognized, it is imperative that experts who apply multi-criteria methodologies such as Bradford Hill or the 'weight of the evidence' rigorously explain how they have weighted the criteria. Otherwise, such methodologies are virtually standardless and their applications to a particular problem

[22] Defendants also argue that Dr. Samet does not seem to employ "the 'same level of intellectual rigor' that he employs in his academic work." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 26 (1st Cir. 2011) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Here, Dr. Samet relies on one epidemiological study with potential confounders. In contrast, Dr. Samet's report to the Surgeon General, which concluded that smoking causes lung cancer, was based upon the consistently strong associations observed in at least seven observational studies. ECF No. 956-1, DX25 (Aug. 8, 2017 Samet Dep.) at 80:3-24.

can prove unacceptably manipulable. Rather than advancing the search for truth, these flexible methodologies may serve as vehicles to support a desired conclusion.").

B. Plaintiffs' Medical Experts Failed to Consider Alternative Explanations

Courts also weigh the ability of an expert to rule out alternative explanations. *Lauzon*, 270 F.3d at 693 (collecting cases). The Eighth Circuit noted that this factor is often cited when discussing a causation opinion arrived at by differential diagnosis. *Id.* at 693 n.7. This factor is also relevant here, though, given the background risk—that is, the risk of infection in the general population when the Bair Hugger has not been used. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005) (noting that "[a] reliable methodology should take into account the background risk").

Although an "expert's causation conclusion should not be excluded because he or she has failed to rule out *every* possible alternative cause," experts should discount "obvious alternatives" and "explain why other conceivable causes are excludable." *Lauzon*, 270 F.3d at 693; *see also* Fed. R. Evid. 702 advisory committee's note to 2000 amendment (experts should "adequately account[] for obvious alternative explanations"). The Court interprets this guidance to require experts at the very least to examine other conceivable causes flagged by researchers in key studies cited in their reports.[23] For

[23] Dr. Samet asserts that the deposition testimony of the Observational Study authors resolves the possibility of confounding. Dr. Samet considered two potential confounders mentioned in McGovern: the prophylactic antibiotic regimen and the thromboprophylaxis protocol, ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 48:20-49:22, which the McGovern authors later confirmed were not confounding factors. *See, e.g.*, ECF No. 1813-39, PX48 (Nov. 29, 2016 Nachtsheim Dep.) at 349:14-25. Dr. Samet, however, never addressed other plausible confounders discussed by the Observational Study researchers in their depositions.

instance, Dr. Reed, a senior author on the Observational Study—the only study establishing an association between the Bair Hugger and infection—testified that many efforts were being undertaken at the hospital at the time of the study to decrease its infection rates and specifically called out one plausible confounder: the introduction of screening for methicillin-sensitive *Staphylococcus Aureus* ("MSSA") at the end of the Bair Hugger only period. ECF No. 751-1, DX8 (Dec. 4, 2016 Reed Dep.) at 78:21-25; 114:7-115:10. In a subsequent study involving Dr. Reed, the researchers recently reiterated that "there were significant confounding factors in [the Observational Study]." ECF No. 1850-1, DX16 (Kumin 2018) at 7.

Dr. Samet, however, never mentioned—let alone investigated—this alternative explanation. ECF No. 1813-2, PX2 (Samet Rpt.) at 12 (summarily concluding that "confounding by other, unidentified factors seems unlikely" because the "change in the warming method was temporally abrupt"). Nor did he examine the raw data underlying the Observational Study to try to confirm whether or not this potential confounder identified by the researchers could be an alternative explanation for the decrease in PJI. ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 41:5-13.[24]

Plaintiffs argue that such failures go to weight and not admissibility. This would be true had Dr. Samet opined, for example, on why MSSA screening is not an alternative

[24] In *In re Mirena (No. II)*, the district court noted—as evidence that the expert paid only "lip service" to the epidemiological study's confounders—that the expert did "not attempt independently to examine the data underlying that study" or "perform a corrected analysis of [the study] to try to account for [confounding factors]." 341 F. Supp. 3d. at 278.

explanation. But here, Dr. Samet's report offers no explanations about MSSA screening for Defendants to attack on cross examination.[25] *Cf. Lauzon*, 270 F.3d at 694 ("[Defendant] may attack [the expert's] explanations of causation on cross examination, thereby requiring [the expert] to offer valid explanations as to why his conclusion remains reliable.").

Plaintiffs argue that such analysis was unnecessary because the researchers only listed potential confounders as opposed to actual confounders, and all observational studies include these sorts of "pointless" caveats. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration Hearing Tr.) at 93-94. Setting aside whether this is an accurate characterization of observational studies generally, the Court notes that a study now confirms that at least one of these conceivable confounders—MSSA screening—has a statistically significant impact on reducing surgical site infections. In July 2018, Dr. Reed and his colleagues published a study specifically addressing the impact of MSSA screening on PJI, which included deep and superficial infection. The Jeans (2018) study found a significant decrease in the MSSA infection rate after the introduction of the screening program as well as a significant reduction in the overall infection rate. ECF No. 1813-43, PX52 (Jeans 2018) at 4. While noting that "improvement in infection rates

[25] At the motion for reconsideration hearing, Plaintiffs' counsel reiterated that they do not have supplemental expert reports that address the Jeans study because the Court denied Plaintiffs' motion to conduct additional discovery and to supplement expert opinions. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration Hearing Tr.) at 139:22-140:13. However, Dr. Samet relied on Dr. Reed's deposition in his original expert report, which identified MSSA screening as a plausible confounder, and so this does not explain why Dr. Samet failed to examine MSSA screening in his initial expert report.

could have been down [sic] to other factors . . .," the authors concluded that the "dramatic reduction in MSSA SSI [surgical site infections] . . . suggests that screening and decolonization was responsible." *Id.*

The parties dispute whether the Jeans study confirms that the introduction of MSSA screening confounded the Observational Study. Dr. Jarvis stated in an affidavit that "the Jeans Study does not 'suggest' that MSSA screening confounded the McGovern study." ECF No. 1916-2, PX75 (Jarvis Aff.) at 2. Further, Dr. Samet stated in an affidavit that the Jeans study does not change his opinion that the Bair Hugger is a substantial contributing cause of PJI. ECF No. 1916-1, PX74 (Samet Aff.) at 3.[26]

The Court need not determine whether or not Jeans actually establishes that MSSA screening confounded the Observational Study. *Mead Johnson*, 754 F.3d at 562 ("district courts are admonished not to weigh or assess the correctness of competing expert opinions"). The Court merely finds that Jeans confirms that Plaintiffs' medical experts failed to examine conceivable alternative explanations acknowledged by the Observational Study authors in their depositions.

[26] In response to Defendants' motion for reconsideration, Plaintiffs' counsel had argued that Jeans does not confound McGovern. On May 16, 2019, Plaintiffs' counsel filed an affidavit by Dr. Samet, which for the first time considered whether "MSSA screening might have affected the findings on the type of warming device in the study by McGovern." ECF No. 1916-1, PX74 (May 14, 2019 Samet Aff.) ¶ 2. Dr. Samet's last-minute analysis was raised solely to support Plaintiffs' argument that Jeans does not confound McGovern. His analysis does not change the Court's conclusion that the medical experts' methodology was unreliable. The timing of this affidavit only underscores the fact that the experts did not initially examine these issues when becoming the first researchers (of which the Court is aware) to conclude that the Bair Hugger causes PJI.

It is true that Plaintiffs' medical experts "need not rule out every alternative explanation for the observed hospital's dropoff in infections." ECF No. 1024 (Dec. 13, 2017 *Daubert* Order) at 9; *see also Mead Johnson*, 754 F.3d at 563 (recognizing that the Eighth Circuit has "consistently ruled that experts are not required to rule out all possible causes"). But it is important for Plaintiffs' general causation experts to seriously consider whether an observational study's "alternative explanations in terms of confounding [are] less plausible than the proposed causal link." Federal Judicial Center, *Reference Manual on Scientific Evidence* 221 (3d ed. 2011) (noting the circumstances under which observational studies provide "good evidence"). This is especially true where both the experts and the studies on which they rely have acknowledged multiple mechanisms for CFU to enter a wound site and acknowledged that infections occur even when the Bair Hugger is not used. *See, e.g*, ECF No. 1813-20, PX25 (McGovern 2011) at 7 (noting that infections in knee and hip surgeries occurred when the conductive warming device was used); ECF No. 1813-32, PX38 (Darouiche 2017) at 2 ("[t]he primary source of these airborne microorganisms is the people in the operating room such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)"); ECF No. 1920-1, DX22 (Jan. 12, 2018 Jarvis Dep.) at 74:6-11 (agreeing that infections occur in "lots and lots" of surgeries where the Bair Hugger is not used).

C. The Causal Inferences Made by Plaintiffs' Medical Experts Have Not Been Generally Accepted by the Scientific Community

Additionally, the Supreme Court in *Daubert* directed courts consider whether the theory has attracted "widespread acceptance within a relevant scientific community. 509 U.S. at 594. For instance, "a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." *Id.* at 594 (citations omitted). The Eighth Circuit cautioned, however, that this factor "must be weighed with the Supreme Court's admonition that 'a rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony.'" *Lauzon*, 270 F.3d at 691 (quoting *Daubert*, 509 U.S. at 588).

Here, the medical and scientific community has repeatedly rejected the causal inferences made by Plaintiffs' experts.[27] In 2013, the International Consensus Meeting ("ICM") on Periprosthetic Joint Infection, which involved more than 400 experts in musculoskeletal infection from 52 countries, reached a "strong consensus" (89% agree, 5% disagree, 6% abstain) as follows: "We recognize the theoretical risk posed by FAW [forced-air warming] blankets and that no studies have shown an increase in SSI [surgical site infections] related to the use of these devices. We recommend further study but no

[27] At the motion for reconsideration hearing, Plaintiffs argued that other scientists agree with their experts' causation conclusions. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration Hearing Tr.) at 122:17-123:24. For support, Plaintiffs' counsel referred to statements reflected in 3M's internal documents but did not attach as evidence the actual statements from the scientists. Thus, from this evidence, the Court is unable to determine the extent that these scientists support the experts' conclusions.

change to current practice." ECF No. 751-2, DX18 (ICM 2013) at 31. In 2017, the FDA reviewed available data and literature, was "unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection," and continued to recommend use of forced-air warming systems. ECF No. 751-1, DX1 (Aug. 30, 2017 FDA letter) at 2. In 2018, the ICM on Musculoskeletal Infection reached a strong consensus (93% agree, 2% disagree, 5% abstain) that "[t]here is no evidence to definitively link [forced-air warming] to an increased risk of SSIs/PJIs." ECF No. 1720-1, DX2 (ICM 2018) at 12.

The Court recognizes that Plaintiffs do not need *definitive* proof of causation. But "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *In re Mirena*, 169 F. Supp. 3d at 450 (quoting *Anderson v. Bristol Myers Squibb Co.*, No. 95-CV-03, 1998 WL 35178199, at *12 (S.D. Tex. Apr. 20, 1998)) ("[I]t is not that experts are 'insincere in their opinions or that their opinions may not some day be validated through scientific research and experiment; it is simply that the law cannot wait for such a confirmation.'"). The fact that the medical and scientific community has rejected these causal inferences further supports the Court's conclusion that there is too great an analytical gap between the evidence and the expert's conclusions.

D. Conclusion

For these reasons, the Court finds that that the medical experts have repeatedly used the scientific literature to reach conclusions rejected by researchers, and therefore,

there is too great an analytical gap between the experts' opinions and the literature.[28] Thus, the Court excludes the experts' general causation opinions and unsupported extrapolations that the Bair Hugger causes PJI.

III. SUMMARY JUDGMENT

Plaintiffs brought several causes of action against Defendants.[29] Plaintiffs rely entirely on the testimony of the three medical experts to establish general causation and testify that the Bair Hugger system can be "ruled in" as the likely cause of Plaintiffs' alleged injuries. For the reasons stated above, the Court granted Defendants' motion to exclude the testimony of Plaintiffs' general causation experts. Without testimony from Plaintiffs' medical experts, Plaintiffs fail to raise a genuine issue of material fact regarding causation. *See Glastetter*, 252 F.3d at 990 (affirming summary judgment for

[28] The Court also notes that Defendants argue that Plaintiffs' experts' treatment of the discredited Augustine study demonstrates their failure to carefully scrutinize the peer-reviewed studies in their reports. Although the experts did not rely on Augustine's study in their reports, Dr. Samet did testify that the Augustine study "corroborates" McGovern and bolsters its reliability. ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 34:24-35:4 (testifying that he regards Augustine's article as "another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison"); 165:13-24 (if McGovern was taken out of consideration, he would point to Augustine's study as providing another estimate of the risk).

[29] (1) Negligence, (2) Strict Liability (failure to warn, defective design and manufacture), (3) Breach of Express Warranty, (4) Breach of Implied Warranty, (5) Violation of the Minnesota Prevention of Consumer Fraud Act, (6) Violation of the Minnesota Deceptive Trade Practices Act, (7) Violation of the Minnesota Unlawful Trade Practices Act, (8) Violation of the Minnesota False Advertising Act, (9) Consumer Fraud and/or Unfair and Deceptive Trade Practices Under State Law, (10) Negligent Misrepresentation, (11) Fraudulent Misrepresentation, (12) Fraudulent Concealment, (13) Loss of Consortium, and (14) Unjust Enrichment.

defendant where plaintiff failed to come forward with admissible "rule in" expert testimony).

Plaintiffs' remaining engineering experts are not qualified to offer an opinion about the cause of surgical infections and cannot answer the threshold "rule in" question of whether the Bair Hugger system actually causes surgical infections. Plaintiffs' engineering experts may propose a causal mechanism, but even where an expert articulates a theory of causation that "appears sound," expert testimony is not admissible where the "major premise remains unproven." *Glastetter*, 252 F.3d at 989; *see also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 498-99 (E.D. Pa. 2016), *aff'd*, 858 F.3d 787 (3d Cir. 2017) ("Causation must be based upon more than a possibility.").

Whether the Bair Hugger is capable of causing PJI is a medically complex question outside of lay jurors' knowledge and experience. Because Plaintiffs' claims arise from "sophisticated" injuries, which require "surgical intervention or other highly scientific technique for diagnosis," proof of causation must be established through expert testimony. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000). "While the specific language used by courts vary to some degree, all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No. II)*, 227 F. Supp. 3d 452, 469 (D.S.C. Jan. 3, 2017), *aff'd*, 892 F.3d 624 (4th Cir. 2018) (collecting cases). Because Plaintiffs have failed to

produce admissible expert testimony that the Bair Hugger causes PJI, Defendants' motion for summary judgment must be granted.

Plaintiffs concede that many of their claims require proof of causation but argue that their unjust enrichment and consumer protection claims do not. Yet, Plaintiffs' unjust enrichment claim also fails. Although an unjust enrichment claim does not explicitly require a showing of causation, causation is an implicit element of this claim because Plaintiffs must prove that Defendants received a benefit under circumstances that would make retention of the benefit unjust. ECF No. 46-1, Master Long Form Compl. ¶¶ 196, 198 ("It is unjust to allow Defendants to earn revenues and retain the benefits and profits from the Bair Hugger while Plaintiffs suffered injuries and damages as stated herein."); *see, e.g, Cromeans v. Morgan Keegan & Co., Inc.*, 303 F.R.D. 543, 558 (W.D. Mo. 2014) ("While each state in the United States describes unjust enrichment differently, the essence of such claims is that the defendant obtained a benefit, the plaintiff suffered an economic detriment as a result, and it would be inequitable for the defendant to keep the benefit under the circumstances.")). In light of the dearth of reliable evidence that the Bair Hugger causes infection, there is nothing in the record to suggest that Defendants received anything of value under inequitable circumstances. *See In re Viagra*, 658 F. Supp. 2d at 969 (granting summary judgment in defendant's favor for the same reasons). Accordingly, the Court grants Defendants' motion for summary judgment on Plaintiffs' unjust enrichment claim.

Causation is also an implied requirement for Plaintiffs' consumer protection claims. Plaintiffs must establish that they used the Bair Hugger and suffered

ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws. ECF No. 46-1, Master Long Form Compl. ¶ 156. Minnesota's consumer protection claims similarly require Plaintiffs to show that "[a]s a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections." *Id.* ¶¶ 129, 134, 143, 151. Because Plaintiffs lack reliable evidence that the Bair Hugger causes infection, Plaintiffs cannot establish that they suffered an injury as a result of Defendants' actions. For this same reason, Plaintiffs would also lack standing to pursue their claims, unless there is a "causal connection between the injury and the conduct complained of." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Therefore, the Court also grants Defendants' motion for summary judgment on Plaintiffs' consumer protection claims.

The Court will issue a separate order that is consistent with this Memorandum.

Dated: July 31, 2019

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge